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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/523,016

11/03/2005

David Farrar

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03/19/2008

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EXAMINER

SANDERS, KRIELLION ANTIONETTE

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

03/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/523,016 | Applicant(s) FARRAR ET AL. | |
| | Examiner Kriellion A. Sanders | Art Unit 1796 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At line 2, "sale" should be --salt--.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 8-13 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/44228 to Green et al. or the equivalent patent to Green et al., U.S. Patent No. 6,833,406 in view of Farrar et al, U.S. Patent No. 5,171,781.

Applicant's invention relates to products and a process of making a dry powder formed of primary particles or aggregates of primary particles, of a polymer wherein:

The primary particles have a size below 20um and

The powder can dissolve or swell in water to form a clear gel,

The process comprising:

Forming an emulsion of aqueous ethylenically unsaturated cationic monomer in non-aqueous liquid optionally in the presence of an emulsifier,

Initiating polymerization and allowing polymerization to complete,

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Distilling water from the emulsion until the emulsion is substantially dry, the distillation being conducted while maintaining a sufficient amount of non-aqueous liquid in the emulsion to prevent breakage of the emulsion,

Separating the non-aqueous liquid from the polymer particles by a process comprising washing the substantially dry emulsion, or a slurry or cake of dry polymer particles separated from it, with a volatile organic solvent which is a solvent for the non- aqueous liquid and for the emulsifier (if used) and which does not dissolve or swell the polymer particles and which is substantially miscible with water,

Separating the washed polymer particles as a cake or slurry of the polymer particles wetted by the solvent, and

Evaporating the solvent from the cake or slurry and thereby providing the dry powder.

Green et al., discloses liquid, dispersion polymer compositions which comprise microparticles of a hydrophilic, water soluble or swellable polymer, preferably an acrylic-based polymer, dispersed in a silicone polymer fluid and an oil-in-water surfactant. The compositions are useful to prepare microparticulate thickening systems to thicken aqueous or aqueous/organic compositions, particularly for use in personal care and pharmaceutical formulations. The hydrophilic polymer a) is water swellable, i.e. it is sufficiently cross-linked to swell but not dissolve in water. Preferably it is acrylic-based. Also it is preferably anionic or cationic.

The composition comprises:

a) from 40% to 60% by weight of the polymer, wherein the polymer is anionic or cationic and is water swellable.

b) from 25% to 45% by weight of a silicone polymer fluid

c) from 8% to 20% by weight of a surfactant or a surfactant mixture, each based on the total weight of the composition.

More particularly, another aspect of the patentees invention is the provision of utilizing the thickened aqueous or water-containing compositions, in personal care formulations, which comprise a) 0.1% to 8% by weight, preferably 1% to 6% by weight of a liquid dispersion polymer composition as described above, b) 0.1% to 70%, preferably 2% to 35% by weight of additional ingredients, for example personal care ingredients such as cosmetic or pharmaceutical excipients and/or active ingredients and c) 45% to 99% of water or a mixture of water and a water-miscible organic solvent such as a lower alcohol. Such lower alcohols include ethanol, isopropyl alcohol, propylene glycol, di-isopropyl alcohol and other known lower alcohols.

These compositions may be in the form of lotions, creams, salves, gels, milks, sprays, foams or ointments.

The polymers may conveniently be obtained in the form of microparticles having an average particle size in the range of 0.1-2 microns by reverse phase emulsion polymerization of suitable monomers in a hydrophobic liquid, i.e. a liquid which has sufficiently low miscibility with water that it can be used as the non-aqueous phase in a reverse phase polymerization.

Suitable cationic monomers include diallyl dialkyl monomers such as diallyl dimethyl ammonium chloride, but preferably the cationic monomer is a ***dialkylaminoalkyl(meth)acrylate*** or -acrylamide.

The polymer is prepared by conventional reverse phase emulsion procedures, namely by adding 1 part by weight (dry weight) of at least one aqueous ethylenically unsaturated monomer, optionally including a sequesterant and a crosslinking

ethylenically unsaturated monomer, into about 1 to 3 parts by weight of a hydrophobic liquid comprising at least in part a liquid hydrophobic silicone polymer fluid and containing about 0.1 to 0.2 parts of at least one conventional water-in-oil emulsifier having a HLB value below 9.0 and optionally 0.5 to 10.0 parts of a polymeric stabilizer surfactant, with intensive agitation so as to form a substantially stable emulsion of the required fine particle size.

The water and any volatile solvent are then removed from the reverse phase emulsion, for example by distillation under reduced pressure, so as to produce a substantially anhydrous stable dispersion of polymer particles less than 2 microns in size dispersed in the silicone polymer fluid.

About 1.0% to 10.0% by weight, based on the weight of the composition, preferably from 2% to 8% by weight of a nonionic oil-in-water emulsifier having a HLB generally above 7 is added after distillation is complete. Suitable emulsifiers of this type are well known to those skilled in the art. Ethoxylated alcohols are preferred.

It is a further feature of the invention that a suitable polymeric stabilizer surfactant is employed as a processing aid to maintain emulsion integrity through the distillation process and to provide for the final liquid polymer dispersion to be a free flowing liquid, even when it contains high levels of microparticles of the water soluble or swellable dispersed polymer.

Upon stirring the liquid dispersion into an aqueous system, the non-ionic surfactant converts the hydrophobic carrier into an oil-in-water emulsion. At the same time the hydrophilic polymer expands on exposure to water resulting in a smooth and

rapid viscosity increase. Typically the polymer particles swell to give a microparticulate thickening system comprising polymer particles having a typical particle size in the range of 2.5 to 5.0 microns.

The inventive liquid dispersion compositions provide microparticulate thickening systems which give effective thickening to aqueous or aqueous/organic formulations at concentrations of 0.1 to 8.0%, preferably 1% to 6% by weight. In addition however they combine the thickening effect of the liquid dispersion polymer with the advantages of the silicone polymer fluid.

The liquid dispersion polymer compositions are compatible with a wide variety of personal care active ingredients and auxiliaries. Typical formulation examples where the polymers may be used include:

Skin Care formulations including all kind of face and body emulsions like creams, lotions, milks and sprays for caring, cleansing, deodorization and depilation, color cosmetics such as; liquid foundations, liquid eyeshadows, liquid blushers, lipsticks and aqueous mascara's; facial masks, lip balms, skin care formulations like body washes, all kind of shaving products; hand soaps, soap bars and soap liquids.

Hair Care formulations include hair conditioners, hair colorations (permanent, semi-permanent and temporary), styling gels, lotions and creams, shampoos, hair relaxers, hair perms and hair masks.

See the World patent at page 2, last two lines through page 6, second paragraph, all of page 7; page 9, last paragraph, through page 10, third paragraph and the paragraph bridging pages 11 and 12.

Farrar et al discloses a particulate polymeric product comprising particles of a water soluble polymer wherein the particles have a size of below 10 μm and wherein the soluble polymer particles are cross-linked or branched and are made by polymerization of water soluble ethylenically unsaturated monomer or monomer blend. In Example 4 of the patent, a copolymer of acrylamide and dimethylaminoethyl acrylate quaternary salt is made. The dispersion is dried by azeotroping to give a particle size for 90% by weight of total particles, below 3 μm . The particles are precipitated from the dispersion by adding acetone and are then further dried to remove the acetone. While entrained in air, they are sprayed with water containing fumed silica. This has an extremely small particle size and so forms a coating around the polymer particles. The particles become aggregated, and are then partly dried, while entrained in the air and are collected and further dried in a fluidized bed. The resultant aggregates have a size above 150 μm but disintegrate rapidly into the individual particles, and dissolve, upon addition to water. Organic liquids for forming the dispersions are disclosed as vegetable oil and hydrocarbon liquids. Amounts of polymer and water utilized are describes as 30% polymer, up to 40% liquid, and up to 35% water. See col. 12, lines 21-40, col. 13, line 13 through col. 14, line 46 and claim 1.

The references disclose each of the elements and process steps of applicant's claimed invention. The ordinary practitioner at the time of applicant's invention would have found it obvious to derive an appropriate ratio of components for formulating the polymer particles of the invention wherein the concentration of monomer in the dispersion is below 70% by weight based on the weight of monomer and water. The

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patented emulsion contains 35 to 55% by weight of the monomer, 20 to 45% by weight of the volatile non-aqueous liquid and 20 to 40% by weight of the water, all based on the weight of monomer, volatile non-aqueous liquid and water. An emulsion is a type of dispersion therefore, this limitation is obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kriellion A. Sanders whose telephone number is 571-272-1122. The examiner can normally be reached on Monday through Thursday 8:30am-7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kriellion A. Sanders/

Primary Examiner, Art Unit 1796

Kriellion A. Sanders
Primary Examiner
Art Unit 1796

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